REMARKS

In the present Amendment, claims 1, 8, 16, 24 and 25 have been amended to delete the recitation "the fluorine-containing polymer contains no other fluorine than the fluorines contained in the fluoroalkylene block," and to recite that the fluorine-containing polymer is (i) a fluoroalcohol ester of a polycarboxylic acid (A) in which the fluoroalcohol portion is contained as the pendant group containing at least a fluoroalkylene block thereof, and the polycarboxylic acid (A) is contained as the unfluorinated vinyl-based polymer thereof; or (ii) a copolymer composed of a fluoroalcohol ester of a polycarboxylic acid (A) and an alkylalcohol ester of a polycarboxylic acid (B), in which the fluoroalcohol portion is contained as the pendant group containing at least a fluoroalkylene block thereof, and the polycarboxylic acid (A) portion and the polycarboxylic acid (B) portion composes the unfluorinated vinyl-based polymer thereof, and the adhesion layer is formed only on the immobilized enzyme layer. Section 112 support for this amendment may be found, for example, at page 9, lines 4-17; page 41, line 10 to page 42, line 24; and Fig. 5 of the specification.

Claim 29 has been cancelled without prejudice or disclaimer.

Claim 30 has been amended to correct its dependency in view of the cancellation of claim 29.

Claims 35-39 have been amended to improve their form.

No new matter has been added, and entry of the Amendment is respectfully requested.

Upon entry of the Amendment, claims 1-28 and 30-39 will be pending, of which claims 8-15, 24-27, 30-34, 36, 38 and 39 are withdrawn from consideration.

Response to Rejections under 35 U.S.C. § 112

At page 2 of the Action, claims 1-7, 16-23, 28, 35 and 37 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement.

As noted, claims 1, 16, 35 and 37 have been amended to address the Examiner's concern. Accordingly, withdrawal of this § 112 rejection of claims 1-7, 16-23, 28, 35 and 37 is respectfully requested.

At page 3 of the Action, claims 35 and 37 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite.

As noted, claims 35 and 37 have been amended to address the Examiner's concern. Accordingly, withdrawal of this § 112 rejection of claims 35 and 37 is respectfully requested.

Response to Rejections under 35 U.S.C. § 103

1. At page 3 of the Action, claims 1-7, 28 and 35 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over EP 0 969 282 to Matsumoto ("EP '282") in view of U.S. Patent No. 5,696,314 to McCaffrey et al and U.S. Patent No. 5,200,051 to Cozzette et al.

Applicants submit that this rejection should be withdrawn because EP '282, McCaffrey et al and Cozzette et al do not disclose or render obvious the enzyme electrode of the present invention, either alone or in combination.

EP '282 teaches an enzyme electrode comprising: (1) an electrode formed on an insulating substrate; (2) a binding layer (adhesion layer) mainly consisting of a silane coupling agent; (3) an immobilized enzyme layer formed on the binding layer; and (4) a permeation-limiting layer comprising a fluorine-containing polymer having a structure where a pendant

group containing at least a fluoroalkylene block is attached to an unfluorinated vinyl-based polymer.

EP '282 also suggests the possible advantages in connection with use of the binding layer being disposed between the electrode and the immobilized enzyme layer. For instance, as to the binding layer being formed to cover the insulating substrate as well as the electrode, as shown in Figure 1, the binding layer underlying the immobilized enzyme layer may improve adhesiveness (binding strength) of the immobilized enzyme layer to the insulating substrate and the electrode. The binding layer underlying the immobilized enzyme layer is also effective in improving wettability of the surface of the insulating substrate and thickness uniformity during formation of the immobilized enzyme layer in which an enzyme is immobilized.

Although EP '282 suggests that the immobilized enzyme layer inhibits sufficient wettability to form the permeation-limiting layer thereon, EP '282 fails to suggest that the wettability of the immobilized enzyme layer will be insufficient to form the permeation-limiting layer thereon.

The binding layer underlying the immobilized enzyme layer also exhibits selective permeation to ascorbic acid, uric acid and acetaminophen which may interfere with a reaction of hydrogen peroxide on the electrode 2. As the hydrogen peroxide is produced in the immobilized enzyme layer and is detected on the electrode 2, the binding layer underlying the immobilized enzyme layer may be used to selectively permeate the hydrogen peroxide into the electrode 2. On the other hand, the adhesion layer formed on the immobilized enzyme layer is by no means used to selectively permeate the hydrogen peroxide into the electrode 2.

Accordingly, EP '282 suggests that the binding layer (adhesion layer) mainly consisting of a silane coupling agent is highly adhesive to the surface of the insulating substrate and the electrode, and that the immobilized enzyme layer is highly adhesive to the surface of the binding layer (adhesion layer).

However, EP '282 fails to provide any suggestion as to whether or not the layer mainly consisting of a silane coupling agent will be highly adhesive to the surface of the immobilized enzyme layer. EP '282 also fails to provide any suggestion about whether or not the permeation-limiting layer comprising a fluorine-containing polymer having a non-fluorinated vinyl polymer structure will be more adhesive to the surface of the layer mainly consisting of the silane coupling agent than to the surface of the immobilized enzyme layer.

In view of the above facts, EP '282 fails to provide any suggestion as to whether or not the layer mainly consisting of a silane coupling agent may provide further improved adhesiveness (binding strength) of the permeation-limiting layer comprising a fluorine-containing polymer to the immobilized enzyme layer, in comparison with the good adhesiveness (binding strength) attained in the case of the direct contact with each other.

EP '282 fails to provide any suggestion that the adhesivness (binding strength) of the permeation-limiting layer comprising a fluorine-containing polymer to the immobilized enzyme layer is insufficient.

EP '282 fails to provide any suggestion that the wettability of the layer mainly consisting of a silane coupling agent will be better than the wettability of the immobilized enzyme layer.

McCaffrey et al teach a multilayer enzyme electrode in which enzyme/polymer layer 35 is employed to increase the time period over which the blood/aqueous slope sensor is constant, and thus the enzyme/polymer layer 35 should only be disposed in an area above the area defined by the immobilized enzyme layer 20. To this aim, adhesive layer 30 is used to promote adhesion between the enzyme/polymer layer 35 and the immobilized enzyme layer 20 as well as between dielectric layer 25 and microporous layer 40. In addition, or alternatively, adhesive layer 30 is designed to isolate the enzyme/polymer layer from the immobilized enzyme layer 20. Furthermore, the adhesive layer 30 is formed from such a silane coupling agent as aminopropyl-triethoxy silane. See column 7, line 46 to line 59, and column 9, line 20 to line 27.

Accordingly, McCaffrey et al suggest that the adhesive layer 30 made of a silane coupling agent may be adhesive to the surface of the immobilized enzyme layer 20, and that the enzyme/polymer layer 35 is highly adhesive to the surface of the adhesive layer 30. McCaffrey et al also suggest that the adhesive layer 30 made of a silane coupling agent is highly adhesive to the surface of the dielectric layer 25, and that the microporous layer 40 is highly adhesive to the surface of the adhesive layer 30.

However, McCaffrey et al fail to provide any suggestion that the adhesivness (binding strength) of the permeation-limiting layer comprising a fluorine-containing polymer to the adhesive layer made of a silane coupling agent will be better than the adhesiveness (binding strength) of the permeation-limiting layer comprising a fluorine-containing polymer to the immobilized enzyme layer.

Further, McCaffrey et al teaches just a structure in which the adhesive layer 30 made of a silane coupling agent is formed on the immobilized enzyme layer 20 as well as on the dielectric layer 25. Thus, McCaffrey et al fails to provide any suggestion that the adhesive layer made of a silane coupling agent is formed only on the immobilized enzyme layer, but not formed on the dielectric layer.

Cozzette et al teach a biosensor containing multiple layers, in which a silane layer underlying a biolayer (immobilized enzyme layer) is used to improve adhesiveness (binding strength) of the immobilized enzyme layer to an electrode. Further, Cozzette et al teach a process for forming the silane layer on the electrode and an insulating film (i.e. silicon oxide) using a silane coupling agent, in which process a liquid mixture of silane compound with a solvent is applied onto the surface of the electrode and the insulating film. The surface of the electrode and the insulating film lacks "detailed" rough topography that would promote adhesion between component layers. The silane layer formed with silane coupling agent is employed to promote adhesion to the underlying surface that lacks "detailed" rough topography.

Cozzette et al also teach such an additional advantage that the silane layer covering the electrode is used as a semi-permeable solid which promotes adhesion of the immobilized enzyme layer onto the electrode and is able to act as a small-molecule-selective membrane fit to selectively permit hydrogen peroxide produced in the immobilized enzyme layer.

However, Cozzette et al fail to provide any suggestion about whether or not the silane layer formed with silane coupling agent will provide improved adhesion to the surface of the immobilized enzyme layer, in such a case that the immobilized enzyme layer already has

"detailed" rough topography fit to the good adhesion of the permeation-limiting layer comprising a fluorine-containing polymer used in EP '282.

On the other hand, EP '282 discloses that the polymer used for a permeation-limiting layer has a non-fluorinated vinyl polymer structure as a principal chain, which is highly adhesive to the immobilized enzyme layer.

Accordingly, EP '282 by no means suggests that, in comparison with the direct contact of the permeation-limiting layer having a non-fluorinated vinyl polymer structure as a principal chain with the immobilized enzyme layer, the intervening layer mainly consisting of a silane coupling agent may provide further improved adhesiveness (binding strength) of the permeation-limiting layer comprising a fluorine-containing polymer to the immobilized enzyme layer.

Similarly, McCaffrey et al and Cozzette et al fail to suggest any technical merit such that, in comparison with the direct contact of the permeation-limiting layer having a non-fluorinated vinyl polymer structure as a principal chain with the immobilized enzyme layer, the intervening layer mainly consisting of a silane coupling agent would provide further improved adhesiveness (binding strength) of the permeation-limiting layer comprising a fluorine-containing polymer to the immobilized enzyme layer.

As the permeation-limiting layer of EP '282 is made of the polymer being highly adhesive to the immobilized enzyme layer, there is no reasonable need for providing any further layer to promote adhesion between the permeation-limiting layer and the immobilized enzyme layer of EP '282.

In this regard, the combination of EP '282 with McCaffrey et al and Cozzette et al clearly fails to suggest or provide any motivation to use an intervening layer mainly consisting of a silane coupling agent between the permeation-limiting layer and the immobilized enzyme layer of EP '282.

Accordingly, claims 1-7, 28 and 35 as amended are not obvious over EP '282 in view of McCaffrey et al and Cozzette et al.

In view of the above, reconsideration and withdrawal of the § 103(a) rejection of claims 1-7, 28 and 35 based on EP '282 in view of McCaffrey et al and Cozzette et al are respectfully requested.

2. At page 6 of the Action, claims 16-23 and 37 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the references as applied to claims 1-7, 28 and 35 above, and further in view of U.S. Patent No. 6,461,861 to Schillig et al.

Applicants submit that this rejection should be withdrawn because EP '282, McCaffrey et al, Cozzette et al and Schillig et al do not disclose or render obvious the enzyme electrode of the present invention, either alone or in combination.

Schillig et al teach a microbial membrane reactor comprising a membrane sandwiched between opposed surfaces of first and second structural elements, wherein the inner surface of the second element that abuts the membrane is provided with one or more flow channels for flow of the fluid over the surface of the membrane.

Schillig et al teach only a structure in which one or more flow channels are formed on the inner surface of the second element that abuts the membrane. Schillig et al fail to suggest such a

local structure in which the layer having grooves on the outer surface thereof is formed on the immobilized enzyme layer, whereas the inner surface of the second element that abuts the immobilized enzyme layer has no flow channels.

Therefore, the combination of EP '282 with McCaffrey et al, Cozzette et al and Schillig et al fails to provide any suggestion about such a local structure that the outer surface (top surface) of the permeation-limiting layer formed on the adhesion layer has grooves, whereas the inner surface (interface) of the permeation-limiting layer with the adhesion layer has no grooves, so that the grooves formed in the outer surface (top surface) is by no means used as flow channels for flow of the fluid over the surface of the immobilized enzyme layer.

In this view, claims 16-23 and 37 as amended are not obvious over EP '282 in combination with McCaffrey et al, Cozzette et al and Schillig et al.

In view of the above, reconsideration and withdrawal of the § 103(a) rejection of claims 16-23 and 37 based on EP '282 in view of McCaffrey et al and Cozzette et al, and further in view of Schillig et al, are respectfully requested.

Response to the Non-Statutory Obviousness-Type Double Patenting Rejections

1. At pages 7-8 of the Action, claims 1-7, 16-23, 28, 35 and 37 are rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-53 of U. S. Patent No. 6,280,587 to Matsumoto ("Matsumoto '587") in view of McCaffrey et al, Cozzette et al, and Schillig et al.

Matsumoto '587 is the U.S. counterpart application of EP '282. Accordingly, Applicants submit that this rejection should be withdrawn for essentially the same reasons that the §103(a)

rejection based on EP '282 in view of McCaffrey et al, Cozzette et al and Schillig et al should be withdrawn.

2. At page 8 of the Action, claims 1-7, 16-23, 28, 35 and 37 are rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-62 of U. S. Patent No. 6,464,848 to Matsumoto ("Matsumoto '848") in view of EP '282, McCaffrey et al, Cozzette et al and Schillig et al.

Matsumoto '848 teaches an enzyme electrode comprising

an electrode formed on an insulating substrate;

a binding layer (adhesion layer) mainly consisting of a silane coupling agent;

an immobilized enzyme layer formed on the binding layer; and

a permeation-restricting layer (permeation-limiting layer) comprising a fluorine-containing polymer having a structure where a pendant group containing at least a fluoroalkylene block is attached to an unfluorinated vinyl-based polymer.

However, Matsumoto '848 fails to provide any suggestion as to such a modification that an adhesion layer comprising a silane-containing compound (a silane coupling agent) intervenes between the immobilized enzyme layer and the permeation-restricting layer (permeation-limiting layer).

As discussed above, combination of EP '282 with McCaffrey et al and Cozzette et al clearly fails to suggest that, in comparison with the direct contact of the permeation-limiting layer having a non-fluorinated vinyl polymer structure as a principal chain with the immobilized enzyme layer, the intervening layer mainly consisting of a silane coupling agent may provide

further improved adhesiveness (binding strength) of the permeation-limiting layer comprising a fluorine-containing polymer to the immobilized enzyme layer. Therefore, the combination of EP '282 with McCaffrey et al and Cozzette et al clearly fails to suggest any motivation to use an adhesion layer between the permeation-limiting layer and the immobilized enzyme layer of EP '282.

Accordingly, claims 1-7, 16-23, 28, 35 and 37 as amended are not obvious over Matsumoto '848 in combination with EP '282, McCaffrey et al, Cozzette et al and Schilig et al.

In view of the above, reconsideration and withdrawal of the double patenting rejection of claims 1-7, 16-23, 28, 35 and 37 based on Matsumoto '848 in view of EP '282, McCaffrey et al, Cozzette et al and Schilig et al are respectfully requested.

Allowance is respectfully requested. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

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Respectfully submitted,

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